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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/066,436
Filing Date	1/30/2002
First Named Inventor	Steve G. Baker
Art Unit	3738
Examiner Name	Thomas C. Barrett
Total Number of Pages in This Submission: 15	Attorney Docket Number: ENDOV-59271

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment / Reply
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- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
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- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
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- ☐ Petition
- ☐ Petition to Convert a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence
- ☐ Terminal Disclaimer
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- ☐ After Allowance communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☒ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*: **Postcard; Transmittal of Appeal Brief**

Remarks

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	**John V. Hanley** **FULWIDER PATTON LEE & UTECHT, LLP**
Signature	
Date	**2/17/2004**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of

Inventor: Steve G. Baker, et al.

Serial No. 10/066,436

Filed: January 30, 2002

For: THORACIC GRAFT AND DELIVERY SYSTEM

Examiner: Thomas C. Barrett

Group Art Unit: 3738

Client ID/Matter No. ENDOV-59271

February 17, 2004

TRANSMITTAL OF APPEAL BRIEF

MS: Appeal Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith, in triplicate, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on October 17, 2003. This paper is also in response to the January 21, 2004 Notification Of Non-Compliance with 37 CFR 1.192(c) and in furtherance to Appellant's Brief filed on December 17, 2003.

This application is on behalf of EndoVascular Technologies, Inc., a large entity, which is a wholly owned subsidiary of Guidant Corporation.

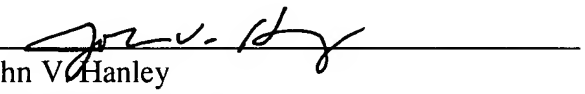
Pursuant to 37 CFR § 1.17(c), the fee for filing the Appeal Brief was submitted along with the Notice of Appeal filed on October 17, 2003. Authorization is hereby provided, however, to charge our Deposit Account No. 06-2425, any fees due in connection with the present appeal.

As this paper is being filed within one month of the date of mailing of the Notification Of Non-Compliance, Applicant believes that no extension of term is required. However, please consider this paper as a conditional petition to provide for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time.

If any additional extension and/or fee is required, this is a request therefor and to charge Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: 

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of

Inventor: Steve G. Baker, et al.

Serial No. 10/066,436

Filed: January 30, 2002

For: THORACIC GRAFT AND DELIVERY SYSTEM

Examiner: Thomas C. Barrett

Group Art Unit: 3738

Client ID/Matter No. ENDOV-59271

February 17, 2004

APPELLANT'S BRIEF (CFR § 1.192)

MS: Appeal Brief Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This brief is being filed in response to the January 21, 2004 Notification Of Non-Compliance With 37 CFR 1.192(c) and in furtherance of Appellant's Brief filed on December 17, 2003 and the Notice of Appeal, filed in this case on October 17, 2003. The fees required under § 1.17 were submitted on October 17, 2003. In the event additional fees are required, authorization is hereby provided to charge our Deposit Account No. 06-2425 any fees due in connection with this paper. This brief is being transmitted in triplicate.

This brief contains items under the following headings, and in the order set forth below:

I. REAL PARTY IN INTEREST

II. RELATED APPEALS AND INTERFERENCES

III. STATUS OF CLAIMS

IV. STATUS OF PROSECUTION

V. SUMMARY OF INVENTION – CONCISE EXPLANATION OF CLAIMED INVENTION

VI. ISSUES

VII. GROUPING OF CLAIMS

VIII. ARGUMENTS

The final page of this brief bears the practitioner's signature.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the following party: EndoVascular Technologies, Inc., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a wholly-owned subsidiary of Guidant Corporation, 111 Monument Circle, 29th Floor, Indianapolis, IN 46204-5129.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the applicant.

III. STATUS OF CLAIMS

The status of the claims in this application are:

A. Total Number of Claims in the Application

The claims in the application are: Claims 22-32

B. Status of All of the Claims

Each of pending claims 22-32 stand as finally rejected under 35 U.S.C. § 103(a).

C. Claims on Appeals

The claims on appeal are each of pending claims 22-32.

IV. STATUS OF PROSECUTION

On June 17, 2003, claims 22-24, 27 and 30-32 were finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Lazarus et al. (U.S. 5,275,622; Exhibit A) in view of Rhodes (U.S. 5,122,154; Exhibit B). Additionally, claims 22, 25, 26, 28 and 29 were finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Rhodes in view of Lazarus et al.

In response thereto, the Applicants filed a paper dated August 18, 2003 arguing for the allowance of the pending claims. Subsequently, the Examiner issued an Advisory Action on August 29, 2003. The August 2003 Advisory Action indicated that the Examiner did not believe that Applicants' arguments were persuasive.

V. SUMMARY OF INVENTION – CONCISE EXPLANATION OF CLAIMED INVENTION

The invention of the present application relates to both a prosthesis and a system for implanting a prosthesis within vasculature. In the form of a graft assembly, the prosthesis is contemplated to be configured for repairing a diseased condition of vasculature (p. 4, lns. 4-12).

In one particular embodiment, the graft assembly includes a graft having a length, a first end and a second end (p. 32, ln. 14 et seq.). A plurality of unconnected and discrete frames are

attached to the graft substantially along the length of the graft (FIG. 25; reference characters 55, 175, 176; p. 26, lns. 17-20). Each frame defines a ring and includes a plurality of alternating apices (See generally p. 26, ln. 13 et seq.). Significantly, the frames can be self-expanding and can embody spring forces to securely attach the graft assembly within vasculature (See generally p. 27, ln. 34 et seq.). A plurality of self-expanding frames can be stacked from end to end along the length of the graft.

Moreover, the frames of the graft assembly serve to yieldably urge a tubular graft from a first compressed or collapsed position to a second expanded position and provides a fluid tight seal between the graft and the vasculature (FIGS. 36-41; p. 25, lns. 18-33). Notably, the diameter of the graft assembly can be selected to be larger both in length and diameter than the area of vasculature into which it is to be placed (p. 32, lns. 14-33).

Accordingly, as it will be developed below, it is believed that a graft assembly including a graft and a plurality of unconnected and self-expanding discrete frames at least one of which is self-expanding, was an advancement over the art in the 1994 timeframe. It is also believed that such a graft assembly is also patentable over the cited art.

VI. ISSUES

Whether claims 22-24, 27 and 30-32 were improperly finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Lazarus, et al. in view of Rhodes and whether claims 22, 25, 26, 28 and 29 were improperly finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Rhodes in view of Lazarus et al.

VII. GROUPING OF CLAIMS

Applicants believe that claims 22-24, 27 and 30-32 should stand together as Group I and claims 22, 25, 26, 28 and 29 form the claims of Group II.

VIII. ARGUMENTS – REJECTION UNDER 35 U.S.C. § 103(a)

A. Overview

A tenet which is highly significant to the prosecution of the present application is set forth in MPEP Section 2143.03. That is, to "establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." In re Rozka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Additionally, it is submitted that as is supported by MPEP Section 2144, by mischaracterizing the cited art, the Examiner has not presented a convincing line of reasoning supporting the rejection of the claims. Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). Since the art appears to lack the teaching of the limitations recited in the claims, should the rejections be based upon facts within the personal knowledge of the Examiner, the data supporting that knowledge should be stated as specifically as possible and the facts relied upon must be supported. Thus, in the event personal knowledge is being relied upon by the Examiner, the Applicant hereby requests an affidavit from the Examiner regarding such personal knowledge (See MPEP Section 2144.03 and 37 CFR 1.104(d)(2)).

Significantly, the Court of Appeals for the Federal Circuit in In re Lee, 61 USPQ 21 1430 (Fed. Cir. 2002) reinforced the obligation of a fact finder to develop evidentiary bases for conclusions concerning the application of art to claims. As to certain limitations recited in each of the pending claims, it is respectfully submitted that no evidentiary basis has been provided for the combination of the cited art and in fact, the cited art teaches away from each other.

B. Group I: Claims 22-24, 27 and 30-32

1. Lazarus et al. in view of Rhodes

Claims 22-24, 27 and 30-32 have been finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Lazarus et al. in view of Rhodes. In rejecting the claims in the final Office action, the Examiner relied upon MPEP 2145 as stating: "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other products for the same use."

It is to be recognized that MPEP 2145 while referencing MPEP 2143.01, also states that there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine referenced teachings. It is additionally noted that MPEP 2143.01 states that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Additionally, "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill in the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facia* case of obviousness without some objective reason to combine the teachings of the references." Further, the MPEP states that "The level of skill in the art cannot be relied upon to provide the suggestion or to combine references."

In rejecting claims 22-24, 27 and 30-32, the Examiner stated that the Lazarus et al. reference discloses a graft including a plurality of non-overlapping self-expanding frames but fails to disclose the frames substantially along the length of the graft. The Rhodes reference was relied upon as teaching discrete frames along a length of a graft. The Examiner then concluded that "It would have been obvious to one of ordinary skill in the art to combine the teaching of

discrete frames along the length of the graft, as taught by Rhodes, to a graft comprising a plurality of frames extending beyond the length of the graft as per Lazarus et al., in order to add strength and flexibility to the graft, enabling use of a larger graft."

The Lazarus et al. reference, however, teaches the use of a graft that consists of a deformable tubular member provided with a continuous wall extending between first and second ends of the graft (See Col. 8, lns. 25 et seq.). One material found to be satisfactory for the continuous wall is DeBakey soft woven Dacron. The tubular member is taught as having a length from 8 to 15 centimeters with 10 centimeters being typical. Further, the length of the tubular member is determined by the size of a patient's anatomy (See Col. 11, lns. 35 et seq.). The size of the graft is in fact taught to be sufficient to span approximately one centimeter both proximal and distal an aneurysm. Hook-like elements provided at the first and second ends of the graft are employed to seat the device within tissue on both sides of an aneurysm.

Notably, the Rhodes reference actually acknowledges that it is the distance between spaced supporting stents which permits a Rhodes graft to flex (See Col. 7, lns. 44-50). Thus, the stents themselves do not add flexibility to a graft.

Significantly, there is no discussion in the Lazarus et al. reference of any problem with length or the ability of spanning an aneurysm nor a need to add strength or flexibility to a graft. In fact, Lazarus et al. teaches spanning an aneurysm by an excess of 1 cm. Therefore, the need for "enabling use of longer graft" is unfounded in Lazarus et al. Moreover, adding "strength and flexibility to the graft" is not described as being desired characteristics. That is, the descriptions of the Lazarus et al. graft make clear the desirability of a deformable graft made from soft woven material. Finally, it is clear from the teachings of the Rhodes reference that flexibility is not

added to a graft by adding a stent or for the purposes of this application, adding a frame, to a graft.

Accordingly, the combination of Lazarus et al. in view of Rhodes to reject claims 22-24, 27 and 30-32 and § 103 is highly flawed. There is no suggestion or motivation in the Lazarus et al. reference to add stents along a length of a graft as taught by Rhodes as a stronger or a longer graft is not a desired or contemplated feature of Lazarus et al. Moreover, there is no objective reason for one of ordinary skill in the art to add frames to a graft since according to the Rhodes reference, doing so does not add flexibility as suggested by the Examiner. Without an objective reason and without a motivation or suggestion to combine the teachings of art, we are left with art being inappropriately combined under MPEP 2143.01.

Thus, it is respectfully submitted that the combination of Lazarus et al. and Rhodes to reject claims 22-24, 27 and 30-32 was made in error.

C. Group II: Claims 22, 25, 26, 28 and 29

Claims 22, 25, 26, 28 and 29 have been finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Rhodes in view of Lazarus.

It is believed to be highly significant to the rejection of Group II claims that MPEP 2143.01 also states that "If the proposed modification or combination of the prior art would change the principle operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facia* obvious."

In this regard, it is believed to be relevant that the In re Ratti (270 F.2d 810; 123 USPQ 349 (CCPA 1959)) case cited for this proposition involved a primary reference which was relied upon in a rejection based upon a combination of references where the primary reference taught that a disclosed device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding that the "suggested combination of

references would require a substantial reconstruction and redesign of elements shown in the [primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate."

It is respectfully submitted that combining the Rhodes and Lazarus et al. references under § 103 is improper because there is no suggestion or motivation, nor an objective reason for the combination. It is particularly improper here since Rhodes is concerned with avoiding the shortcomings of self-expanding structures and specifically teaches a stent formed from rigid links or struts (Col. 6, ln. 33). Therefore, in violation of MPEP 2143.01, modifying Rhodes in view of Lazarus "would change the principal operation of the prior art invention being modified." That is, the combination of teachings employed in the final Office action requires Rhodes to be modified to incorporate a self-expanding frame which is, in fact, the very characteristic Rhodes seeks to avoid.

Notably, the Rhodes patent is concerned with limiting perceived shortcomings associated with self-expanding stent devices (See Col. 2, lns. 30 et seq.). Rhodes teaches that zig-zag stainless wire stents are lacking because the expansion thereof is dependent upon a spring constant and the modules of elasticity of the structure, the same resulting in the possibility of the size of the device changing after implantation. This structure was also said to be problematic in that an undersized structure may not expand sufficiently and become impacted in the arterial wall, thus permitting migration. Moreover, an oversized structure was characterized in the Rhodes reference as being capable of causing a rupture or tear in the vasculature. The Rhodes reference therefore, teaches employing a balloon expandable stent structure formed from rigid struts and consequently actually teaches away from a self-expanding device.

Accordingly, it is respectfully submitted that the reason given by the Examiner for the combination of the Rhodes reference and the Lazarus et al. reference is also flawed. One of ordinary skill in the art would not read the cautions regarding self-expanding structure set forth in Rhodes and then conclude that such structure should be added to the Rhodes graft device.

Therefore, we are again left without a motivation or suggestion to combine the Rhodes and Lazarus et al. references as well as without an objective reason for the combination. Add to that changing the principle operation of the Rhodes device, the conclusion can only be that a *prima facia* case of obviousness has not been made.

Thus, it is respectfully submitted that the combination of Rhodes and Lazarus et al. to reject claims 22, 25, 26, 28 and 29 was made in error.

CONCLUSION

For all the reasons stated above, Applicant respectfully submits that the Examiner has erred in rejecting claims 22-32. It is respectfully requested that the Board reverse the rejection of claims 22-32 and allow claims 22-32 to issue.

Respectfully submitted,

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IX. APPENDIX

Claim 22 (previously presented): A graft assembly for repairing aneurysms, comprising:

a graft having a length, a first end and a second end; and

a plurality of unconnected and discrete frames attached to the graft along substantially the length of the graft, each frame defining a ring and having a plurality of alternating apices and at least one of the plurality of frames being self-expanding.

Claim 23 (previously presented): A graft assembly of claim 22, further comprising at least one wall engaging member attached to one of the plurality of frames.

Claim 24 (previously presented): A graft assembly of claim 23, wherein the wall engaging member is in the form of a hook.

Claim 25 (previously presented): The graft assembly of claim 22, wherein each of the plurality of frames are self-expanding.

Claim 26 (previously presented): The graft assembly of claim 22, further comprising a helix configured at each of the alternating apices.

Claim 27 (previously presented): The graft assembly of claim 22, further comprising a plurality of wall engaging members attached to one of the plurality of frames.

Claim 28 (previously presented): The graft assembly of claim 22, wherein the graft assembly has a tapered profile.

Claim 29 (previously presented): The graft assembly of claim 28, further comprising a longitudinal pleat which provides the graft assembly with a tapered profile.

Claim 30 (previously presented): The graft assembly of claim 22, wherein each of the plurality of frames have a length, each of the frames being configured so as to lack structure overlapping the length of an adjacent frame.

Claim 31 (previously presented): The graft assembly of claim 22, wherein the frames are positioned within an interior of the graft.

Claim 32 (previously presented): The graft assembly of claim 22, wherein a plurality of apices of certain frames extend beyond the length of the graft.